510(k) SUMMARY

NAME & ADDRESS: Dentsply International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
P. J. Lehn Telefax (717) 849-4343

CONTACT:	P. Jeffery Lehn	
DATE PREPARED:	September 10, 2003	
TRADE OR PROPRIETARY NAME:	CLS-2000 UNIT	
CLASSIFICATION NAME:	Steam sterilizer (880.6880)	
PREDICATE DEVICES:	EasyClave™ Steam Sterilizer	K992744

DEVICE DESCRIPTION

The CLS-2000 UNIT is an integrated unit for rinsing, flushing, lubricating, and steam sterilizing dental handpieces, air-motors, and attachments, and for rinsing and steam sterilizing static instruments which are suitable for steam sterilization.

Dental handpieces and instruments are placed in the CLS-2000 UNIT. The CLS-2000 UNIT utilizes water and pulsed steam to rinse and flush the articles. The CLS-2000 UNIT then utilizes saturated steam at elevated pressures in order to attain an effective kill of infectious bio-organisms and prevent cross-contamination. The CLS-2000 UNIT is also equipped with a lubrication feature for the delivery of service oil to dental handpieces, air-motors, and attachments.

INTENDED USE

Rinse, flush, lubricate, and steam sterilize dental handpieces, air-motors, and attachments which are suitable for steam sterilization.

Rinse and steam sterilize dental instruments which are suitable for steam sterilization.

Steam sterilization at 134°C and 3.1 bar absolute for ten minutes.

Maximum load is six (6) dental handpieces (highspeed handpieces, air-motors, and/or attachments) or five (5) dental instruments.

Sterility of devices is compromised on exposure to a non-sterile environment.

TECHNOLOGICAL CHARACTERISTICS

Operating Principle and Energy Type:

The CLS-2000 UNIT uses electrical energy to heat water into steam that is passed into the sterilization chamber. (Substantially equivalent to the EasyClave.)

The CLS-2000 UNIT uses compressed air to drive water and lubricant through lumens of the articles being processed.

Sources of Energy:

The CLS-200 UNIT requires 115 VAC, 60 Hz, and also requires compressed air. (Substantially equivalent to the EasyClave.)

Software or Firmware:

The CLS-2000 UNIT is operated by firmware. (Substantially equivalent to the EasyClave.)

Materials of Construction:

Stainless steel sterilization chamber; electronic circuit boards; electric heat element; plastic and metal support structures and external housing. (Substantially equivalent to the EasyClave.)

Valves and internal plumbing of various conventional materials. (Substantially equivalent to the EasyClave.)

Testing

The CLS-2000 UNIT was tested according to the FDA's Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities.

Physical testing included temperature profiling per section 5.4.2 of AAMI ST55.

Biological testing with *Geobacillus Stearothermophilus* spores included the following, and all biological testing met the end-point criteria of no positives.

- half-cycle testing, replicates, with and without lubricant
- full-cycle simulated use testing
- in-use testing

Other Characteristics

There are no known materials in this device which would create a biocompatibility hazard. The device itself does not contact the patient. Dental handpieces and instruments placed in the device contact only stainless steel and elastomeric o-rings.

The fluids (steam, air, water, and lubricating oil) which flow through the device and into the dental handpieces touch only standard engineering materials (stainless steel, PTFE, plated brass) with no known biocompatibility hazard.

The Unit does not use any cleaning agents, detergents, or other chemicals. The sole washing agent is distilled or de-ionized water provided by the user.

The lubricant used will be at the discretion of the user, since the CLS-2000 lubricant reservoir will accept any liquid lubricant.

We conclude that the CLS-2000 UNIT is substantially equivalent to the EasyClave, and that the data provided herein and previously support the safety and effectiveness of the CLS-2000 UNIT for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2003

Ms. P Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K024133
Trade/Device Name: CLS-2000 Unit
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: August 11, 2003
Received: August 12, 2003

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

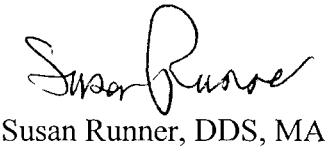
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K024133

Device Name: CLS-2000 UNIT

Indications for Use:

- Rinse, flush, lubricate and steam sterilize dental handpieces, air-motors, and attachments which are suitable for steam sterilization
- Rinse and steam sterilize dental instruments which are suitable for steam sterilization
- Steam sterilization at 134°C and 3.1 bar absolute for ten minutes
- Maximum load is six (6) dental handpieces (highspeed handpieces, air-motors, and/or attachments) or five (5) dental instruments
- Sterility of devices is compromised on exposure to a non-sterile environment

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024133

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

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